



Vermont Health Access
Pharmacy Benefit Management Program
DUR Board Meeting Minutes: 11/13/07

Board Members:

Michael Scovner, M.D., Chair
Andrew Miller, R. Ph.
Kathleen Boland, Pharm.D.

Rich Harvie, R.Ph.
Norman Ward, M.D.
Cheryl Gibson, M.D.

Lynne Vezina, R.Ph.
Frank Landry, M.D.
Stuart Graves, M.D.
Virginia Hood, M.D.

Staff:

Ann Rugg, OVHA
Diane Neal, R.Ph., (MHP)
Jennifer Mullikin, OVHA

Nancy Miner, (MHP)
Robin Farnsworth, OVHA

Judy Jamieson, OVHA
Stacey Baker, OVHA

Guests:

Amy Finn, Merck
Carl Marchand, AstraZeneca
Carl Pepe, GSK
Carl Possidente, Pfizer
Christine Tynun, BIPI
David Canepa, Schering Plough

Ed MacMillan, Abbott Diabetes
Karen Roddy, Lifescan
Keith Osburn, Sepracor
Keith White, Genentech
Laurie Mohler, AstraZeneca
Lyndon Braun, Santarus

Mary Kaysen, Takeda
Michael Nelson, Novartis
Scott Williams, OMJ
Steven Berardino, Amgen
Tom Middleton, OMJ
Tony Severoni, Sepracor, Inc.

Michael Scovner, M.D., Chair, called the meeting to order at 6:59 p.m. at the DUR Board meeting site in Williston.

1. Executive Session:

- An executive session was held from 6:30 until 7:00 p.m. to discuss Medicaid OBRA'90/Supplemental Rebates and Agreements as provided by 33 VSA § 1998(f)(2).

2. Introductions and Approval of DUR Board Minutes:

- Introductions were made around the table.
- The October 2007 meeting minutes were accepted as printed.

Public Comment: No public comment.

3. OVHA Pharmacy Administration Updates: Ann Rugg - Deputy Director, OVHA

- Catamount Health and Employer Sponsored Insurance Programs (Green Mountain Care): Several new health insurance programs that became effective 11/01/07 and include some prescription coverage were described.
- Pharmaceutical Company Sponsored Literature Distributed in Physician Offices: No material should be left in prescribers' offices describing the formulary status of their products with Vermont Medicaid. OVHA considers this an inappropriate activity and will be sending letters to the companies

that continue to distribute this literature. In some instances, the information was found to be inaccurate.

4. Medical Director Update:

- No Medical Director update.

5. Follow-up items from Previous Meeting: Diane Neal, R.Ph., MedMetrics Health Partners (MHP)

- Reclast® Injection (zoledronic acid)-Duration of Drug Interactions:

At the request of the DUR board at the October meeting, MedMetrics researched the question of how long a prescriber should be concerned about drug interactions with Reclast® which is administered once yearly. No drug interaction studies with Reclast® have been conducted and there is no data available that would help answer the question. The Medical Information Department at Novartis stated that they assumed the drug interactions with aminoglycosides, loop diuretics, and other nephrotoxic drugs would be most concerning early after administration because they are thought to be caused by additive effects (changes in calcium levels/nephrotoxicity) that occur early after Reclast® administration.

Public Comment: No public comment.

Board Decision: None needed.

6. Clinical Update: Drug Reviews: Diane Neal, R.Ph.(MHP)

Note: All drug/criteria decisions will be reflected in the next PDL and/or Clinical Criteria update unless otherwise stated.

- Veramyst® Nasal Spray (fluticasone furoate) - Not recommended for addition to the PDL. Coverage would require PA with the criteria for approval being that the patient has had a documented side effect, allergy, or treatment failure to at least two preferred nasal glucocorticoids.

Public Comment: Edward Kent Jr., M.D. – Submitted an email asking the DUR Board to consider adding Veramyst® to the OVHA formulary.

Steve Eggleston, GSK - Commented on the differences between fluticasone furoate and fluticasone propionate, the improvement in ocular symptoms with Veramyst® as well as unique features of the delivery device.

Board Decision: The Board approved the MHP recommendations as described.

- Exforge® (amlodipine/valsartan) - Recommended for addition to the PDL as preferred after the following clinical criteria are met: the patient has been started and stabilized on the requested medication (Note: samples are not considered adequate justification for stabilization) or the patient has had a documented side effect, allergy, or treatment failure to an angiotensin converting enzyme inhibitor (ACEI), an ACEI combination or any other angiotensin receptor blocker (ARB) or ARB combination. A quantity limit of one tablet per day was recommended.

Public Comment: Bob Clark, Novartis and Chris Lyman, Pharm.D., Novartis – Commented on the reduction of edema with the combination product and its use in stage 2 hypertension. Additional safety studies are ongoing.

Board Decision: The Board approved the MHP recommendations noted above.

7. Review of Newly-Developed/Revised Clinical Coverage Criteria: *Diane Neal, R.Ph, (MHP)*

- Analgesics: Short Acting Narcotics (Actiq[®] and Fentora[®]):
The clinical criteria for Actiq[®] and Fentora[®] were clarified to define “opioid tolerant”. Additionally, a criterion was added that would specify that these dosage forms might be suitable in a patient unable to use tablet or liquid formulations. It was recommended that Actiq[®] and Fentora[®] no longer have a distinct clinical category, but that their clinical criteria are incorporated into the category of Analgesics: Short Acting Narcotics.

Public Comment: No public comment.

Board Decision: The revised clinical criteria and merging of categories were unanimously accepted as presented.

- Anti-Diabetic: Oral: Thiazolidinediones (TZDs) and Combinations: (Effective 01/01/08)
It was recommended that the thiazolidinediones and TZD combinations move from unrestricted preferred to preferred after clinical criteria are met. The criteria for approval would be: the patient has been started and stabilized on the requested medication or the patient has had a documented side effect, allergy or treatment failure with metformin. It was also recommended that Duetact[®] move from PA required to preferred after clinical criteria are met with the other medications in this category.

Public Comment: No public comment.

Board Decision: The updated table and revised criteria were accepted with the request to add the phrase “contraindication to metformin” in the criteria.

- Anti-Diabetics: Oral: Dipeptidyl Peptidase (DPP-4) Inhibitors: (Effective 01/01/08)
DDP-4 inhibitors now will appear in the table in a similar manner to the thiazolidinediones above as “preferred after clinical criteria are met”. There will be a 180 day look-back for prior metformin therapy.

Public Comment: No public comment.

Board Decision: The updated table was accepted with the request from the Board to add the phrase “contraindication to metformin” in the criteria.

- Anti-hypertensive: ACE Inhibitor/ACEI Combinations: (Effective 01/01/08)
It was recommended that the generic benazepril/amlodipine become our preferred medication in the ACE Inhibitor/Calcium Channel Blocker category and that both brand name Lotrel[®] and Tarka[®] become PA required. Current users of Tarka[®] would be grandfathered. The sentence “If a medication has an AB rated generic, the trial must be the generic formulation” would be added to the criteria for approval for PA requiring medications.

Public Comment: No public comment.

Board Decision: The Board approved the updated table and revised clinical criteria as recommended.

- Anti-hypertensives: ARBs and ARB Combinations: (Effective 01/01/08)

It was recommended that Avapro[®] (irbesartan) and Avalide[®] (irbesartan/hydrochlorothiazide) move from PA required to preferred after clinical criteria are met. This offers more options to prescribers within these classes at a cost similar to other products.

Public Comment: No public comment.

Board Decision: The Board approved the MHP recommendations noted above.

- Anti-hypertensives: Calcium Channel Blockers: (Effective 12/01/07 and 01/01/08 as noted)

It was recommended that generic amlodipine move to preferred and brand name Norvasc[®] move to PA required effective 12/01/07. It was recommended that generic nimodipine move to preferred and brand name Nimotop[®] move to PA required effective 12/01/07. It was also recommended that Sular[®] move to PA required effective 01/01/08 with grandfathering of current users.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the MHP recommendations noted above.

- Chemical Dependency: Buprenorphine:

It was recommended that a patient specific PA be required for all patients new to buprenorphine therapy (no prescription within last 30 days) rather than physicians being approved generally for prescribing. It was recommended that the criteria for approval be: diagnosis of opiate dependence confirmed (will not be approved for alleviation of pain) and the prescriber has an “X” DEA license in order to prescribe and if Subutex[®] is being requested – the patient is either pregnant (duration of PA will be one month post anticipated delivery date) or the patient has a documented allergic reaction to naloxone supported by medical record documentation. The duration of PA to be one year or one month post anticipated delivery date (if applicable).

Public Comment: No public comment.

Board Decision: The revised clinical criteria and Prior Authorization form were accepted with the added Board request to allow telephone PA requests.

- Chemical Dependency: Vivitrol[®]:

It was recommended that the PA form be faxed to the MedMetrics Clinical Call Center rather than the Medical Director for consideration. This will allow the Medical Director to be available to evaluate second reconsideration requests for Vivitrol[®] should the need arise. Several questions were removed from the PA form as they were not felt to add value or useful information for the prior authorization consideration. The criterion that the patient should be opiate free for > 7 -10 days prior to initiation of Vivitrol[®] was recommended for addition.

Public Comment: No public comment.

Board Decision: The revised clinical criteria and Prior Authorization form were accepted as presented.

- Pulmonary: Inhaled Glucocorticoids: (Effective 01/01/08)

It was recommended that Pulmicort Flexhaler[®] move to preferred and QVAR[®] move to PA required with grandfathering of current users. No change in clinical criteria was recommended.

Public Comment: No public comment.

Board Decision: The Board approved the MHP recommendations noted above.

▪ Pulmonary: Nasal Glucocorticoids: (Effective 01/01/08)

It was recommended that generic fluticasone propionate move to preferred and brand Flonase[®] move to PA required. No change in clinical criteria was recommended.

Public Comment: No public comment.

Board Decision: The Board approved the MHP recommendations noted above.

▪ Urinary Antispasmodics: (Effective 01/01/08)

It was recommended that generic oxybutynin XL move to preferred and brand Ditropan XL[®] move to PA required. The clinical criteria were modified to reflect this change.

Public Comment: No public comment.

Board Decision: The Board approved the revised clinical criteria and other MHP recommendations noted above.

▪ Vaginal: Anti-infectives: (Effective 01/01/08)

It was recommended that generic metronidazole vaginal gel 0.75 % and Vandazole[®] move to preferred and brand Metrogel Vaginal[®] move to PA required.

Public Comment: No public comment.

Board Decision: The Board approved the MHP recommendations noted above.

8. New Drug Classes:

▪ Diabetic Testing Supplies: (Effective early February 2008)

It was recommended that the preferred diabetic monitors/meters and test strips be limited to those supplied by Abbott and Lifescan. The monitors/meters that would be preferred would include Freestyle Lite[®] System Kit, Freestyle Flash[®] System Kit, Freestyle Freedom[®] System Kit, One Touch[®] Ultra 2 Kit, One Touch[®] Ultra Mini Kit, One Touch[®] Ultra Smart Kit and Precision Xtra[®] Meter. The preferred test strips would be those test strips used with the listed monitors/meters. All other brands of meters and test strips would be non-preferred. Criteria for approval of the non-preferred products would be that the prescriber demonstrates that the patient has a medical necessity for clinically significant features that are not available on any of the preferred meters/test strips. Letters will be sent to physicians in the first week of January with a list of their patients on non-preferred products. As well, letters will be sent that same week to pharmacies alerting them to this upcoming change with a list of the preferred products and their NDCs. The following week letters will be sent to patients who are currently using non-preferred products alerting them to the change and providing them with “800” phone numbers to call or a web site to visit to obtain a free meter. Meters will also be available by coupon in pharmacies and in physician offices. A block will be placed on the PA required NDCs approximately 4 weeks after the letter reaches patients. It will be stressed to the patients that they need to know the name of the new meter they are using so that they are sure to obtain the appropriate test strips and that the pharmacy will be best positioned to help them with this if the patient obtains the meter at the pharmacy.

Public Comment: Karen Roddy, Lifescan and Ed MacMillan, Abbott Diabetes - Commented on the experience of other states making a similar switch and the assistance that the companies would provide in rolling out this change.

Board Decision: The Board approved the MHP recommendations noted above and requested that the length of authorization be lengthened to 5 years.

9. RetroDUR: Diane Neal, R.Ph, (MHP)

▪ Suboxone®/Subutex®:

An overview of buprenorphine utilization was presented including Suboxone® vs. Subutex® distribution by unique utilizers, numbers of paid claims and paid amount as well as a dose distribution analysis and a summary of concomitant opioid use while on buprenorphine. It was recommended that this be revisited in about six months after the roll out of the new clinical criteria and prior authorization request form discussed above.

Public Comment: No public comment.

Board Decision: None needed.

▪ Asthma:

Work has begun on a RetroDUR that will examine drug therapy pre and post admission to an Emergency Department or inpatient hospital unit with a primary diagnosis of asthma exacerbation.

Public Comment: No public comment.

Board Decision: None needed.

▪ Mental Health Drug Use in Children:

A RetroDUR is planned for presentation at the December 2007 meeting. A summary of mental health drug use in patients stratified by ages 0 – 6 years, 7 – 12 years and 13 – 17 years old will be presented.

Public Comment: No public comment.

Board Decision: None needed.

10. Plan Exclusions: Diane Neal, R.Ph, (MHP)

- New drug products released on the market are reviewed every 2 weeks by MedMetrics Health Partners to determine pharmacy benefit coding according to the current PDL. A variety of products released on the market are not in a drug class that is currently managed or are not specifically addressed in the PDL. As approved by the DUR Board, drug products that appear to be illogical combinations, kits containing non-drug items or very expensive dosage forms where inexpensive alternatives exist are temporarily blocked and brought to the DUR Board on a periodic basis for approval of permanent block or a decision to unblock. The presented table highlights drug products blocked from drug files dated 09/27/07 - 10/11/07. DUR Board members were asked to comment if they felt that a drug product should not be blocked.

Public Comment: No public comment.

Board Decision: None needed.

11. Updated New-to-Market Monitoring Log: *Diane Neal, R.Ph, (MHP)*

- This log shows new entries in the market highlighted in red. The log is informational only. Suggested dates for review are to be used as a guide only. The actual date of review will depend on the complexity of the agenda.

Public Comment: No public comment.

12. General Announcements: *Diane Neal, R.Ph, (MHP)*

FDA Safety Alerts

Byetta[®] (exenatide) - acute pancreatitis: The FDA has reviewed 30 post-marketing reports of acute pancreatitis in patients taking Byetta[®]. An association between Byetta[®] and acute pancreatitis is suspected in some of these cases. The recommendation is that no action is required on the part of the DUR Board in response to this alert. The alert will be posted on the OVHA pharmacy web site.

Public Comment: No public comment.

Board Decision: The Board approved all MHP recommendations.

Phosphodiesterase -5 Inhibitors-sudden hearing loss: The FDA informed healthcare professionals of reports of sudden decreases or loss of hearing following the use of the PDE5 inhibitors Viagra[®], Levitra[®], Cialis[®] for the treatment of erectile dysfunction, and Revatio[®] for the treatment of pulmonary arterial hypertension. In some cases, the sudden hearing loss was accompanied by tinnitus and dizziness. The recommendation is that no action is required on the part of the DUR Board in response to this alert. The alert will be posted on the OVHA pharmacy web site.

Public Comment: No public comment.

Board Decision: The Board approved all MHP recommendations.

Provigil[®] (modafinil) - severe rash: The FDA and Cephalon notified healthcare professionals of updates to the WARNINGS section of the prescribing information for Provigil[®]. The revised labeling updates safety information to include warnings regarding serious rash, including Stevens-Johnson Syndrome (SJS) and hypersensitivity reactions, and psychiatric symptoms. Rare cases of serious or life-threatening rash, including Toxic Epidermal Necrolysis, and Drug Rash with Eosinophilia and Systemic Symptoms have been reported in adults and children in worldwide postmarketing experience. Angioedema and multi-organ hypersensitivity reactions have also been reported in post-marketing experience. The recommendation is that no action is required on the part of the DUR Board in response to this alert. The alert will be posted on the OVHA pharmacy web site.

Public Comment: No public comment.

Board Decision: The Board approved all MHP recommendations.

CellCept® (mycophenolate mofetil) - use in pregnancy: The FDA and Roche notified healthcare providers that use of CellCept® is associated with increased risk of first trimester pregnancy loss and increased risk of congenital malformations, especially external ear and facial abnormalities including cleft lip and palate, and anomalies of the distal limbs, heart, esophagus, and kidney. Based on post-marketing data from the United States National Transplantation Pregnancy Registry and additional post-marketing data collected in women exposed to systemic mycophenolate mofetil during pregnancy, the pregnancy category for CellCept® has been changed from Category C (risk of fetal harm cannot be ruled out) to Category D (positive evidence of fetal risk). MedMetrics looked at claims for patients receiving CellCept® and found no female patients receiving both CellCept® and a prenatal vitamin. The alert will be posted on the OVHA pharmacy web site.

Public Comment: No public comment.

Board Decision: The Board recommended that a patient specific mailing be sent to physicians advising them to discuss contraception with their female patients receiving CellCept®.

13. Adjourn: Meeting adjourned at 9:09 p.m.

Next DUR Board Meeting

Tuesday, December 11, 2007

7:00 - 9:00 p.m.*

EDS Building, OVHA Conference Room

312 Hurricane Lane, Williston, VT

(Entrance is in the rear of the building)

* The Board meeting will begin at 6:30 p.m. and the Board will vote to adjourn to Executive Session to discuss Medicaid OBRA'90/Supplemental Rebates and Agreements as provided by 33 VSA § 1998(f)(2). The Executive Session is closed to the public.